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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/718,188

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EXAMINER

BLATT, ERIC D

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/718,188	<b>Applicant(s)</b> YANUMA ET AL.	
	<b>Examiner</b> Eric Blatt	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 45-47 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17-19, 21, 22, 45 and 46 is/are rejected.
- 7) ☒ Claim(s) 12, 16, 20 and 47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-7 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites, "the X-ray chip is formed in flange shapes outwards with respect to an axis of the second cylindrical member." The language "formed in flange shapes outwards" is unclear and does not appear to be grammatically correct. It seems that claim 3 is intended to be drawn toward element 52 in Figures 1A and 1B which is an X-ray chip having an annular projection wherein the annular projection extends radially outwardly from the outer surface of the second cylindrical member 24. This understanding will be assumed for present purposes of examination.

Claims 45 and 46 recite, "releasing a state of the first cylindrical member held by friction." The first cylindrical member has not been described as being held by friction in the claims or specification, and there appears to be insufficient structure recited in claims 45 and 46 for this method step to be accomplished. Previous to this recitation, all indications in the claim language and the specification suggest that it is the second cylindrical member that is held by friction relative to the forceps channel of the endoscope.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 and 8-11, 13-15, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Randall et al. (US 6,514,261).

Randall discloses a stent delivery system (Figures 1 and 17-20) comprising a first cylindrical member 10 capable of being inserted into a forceps channel of an endoscope, a second cylindrical member 12, 14 inserted within first cylindrical member 10 and capable of advancing/retracting with respect to the first cylindrical member 10, and a stent 16 disposed between the first and second cylindrical members. The second cylindrical member includes a holding mechanism 98, 100 that is capable of holding a relative position of the second cylindrical member with respect to an endoscope. The second cylindrical member 12, 14 includes an x-ray chip 26 recognized at the time of irradiation with an x-ray and disposed in a position where the stent is charged. (Column 3, Lines 43-44) X-ray chip 26 meets the limitations of claim 3 as presently understood.

The holding mechanism 98, 100 is fixed relative to the wire guide port shown at the top of Figures 17, 19, and 20. Second cylindrical member 12 is also fixed relative to said wire guide port. (Column 4, Lines 63-64) Thus, cylindrical member 12 is fixed

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relative to the holding mechanism 98, 100. Holding mechanism 98, 100 comprises a third cylindrical member 100 that is directly slidable on the first cylindrical member 10 outside the first cylindrical member. The third cylindrical member is capable of being inserted into a working channel of an endoscope wherein the working channel has an inner diameter that closely matches the outer diameter of the third cylindrical member 100 such that the third cylindrical member 100 frictionally engages the working channel of the endoscope. Thus, holding mechanism 98, 100 is capable of holding a relative position of the second cylindrical member with respect to the forceps channel of the endoscope.

Regarding claims 9, 10, 13, 14, 17, and 18, the wire guide port is interpreted as a connection member that connects the third cylindrical member 100 to the second cylindrical member 12. Portion 98 of holding mechanism 98, 100 is considered to be a holder 98. Holder 98 is capable of being attached to and disposed on an endoscope.

Regarding 11, 15, and 19, the wire guide port is considered to be a fixing tool which connects the holder to the second cylindrical member. The wire guide port may be disassembled such that at least second cylindrical member 12 may be removed. Thus, the wire guide port connects the holder to the second cylindrical member in a detachably fixed state.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Randall et al. (US 6,514,261).

Randall discloses all elements of claims 21 and 22 as previously discussed except for a hydrophilic lubrication being disposed on the tip end of the first cylindrical member and the tip-end chip 26 of the second cylindrical member. It was notoriously old and well known to provide hydrophilic lubricious coatings on distal portions of minimally invasive devices. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the apparatus of Randall by providing a hydrophilic lubricant on the tip end of the first cylindrical member and the tip-end chip 26 of the second cylindrical member in order to minimize tissue damage as said elements are advanced through a patient's body.

#### ***Allowable Subject Matter***

Claims 12, 16, 20, and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Said claims recite structural elements of a fixing tool that are not fairly taught by the prior art.

#### ***Response to Arguments***

Applicant's arguments filed November 17, 2008 have been fully considered but they are not persuasive.

Regarding the prior art rejections over Randall, Applicant submits, "In present claim 1, a second cylindrical member includes a holding mechanism which defines a

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relative position of the second cylindrical member with respect to an endoscope. On the other hand, considering the equivalent structure in Randall as indicated by the Examiner, the middle tube (tube spring) 12 or the inner tube 14 needs to include a collar 98 of the housing 100, but there is no such disclosure.”

Examiner is unsure how this argument relates to the patentability of the presently pending claims. Applicant's claimed second cylindrical member is considered to read on elements 12 and 14 of Randall while the claimed holding member is considered to read on elements 98 and 100. Elements 12 and 14 are coupled to elements 98 and 100 by means of wire guide port 38 as discussed in the body of the rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gayhart, Jr. (US 5,438,735) discloses a connecting member that is similar to Applicant's claimed fixing tool.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735.

The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric Blatt  
571-272-9735

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734